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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Murali	JASTY	Weston, MA

Additional inventors are being named on the _____ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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OR

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ENCLOSED APPLICATION PARTS ***(check all that apply)***

☑ Specification *Number of Pages* 21
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Respectfully submitted,

SIGNATURE _____

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Date January 23, 2004

REGISTRATION NO. 33,715 *(if appropriate)*

Docket Number: 37697-0083

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TOTAL AMOUNT OF PAYMENT	($) 160.00

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FEE CALCULATION

1. BASIC FILING FEE

Large Fee Code	Entity Fee ($)	Small Fee Code	Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
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2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		x		=	
Independent Claims		-3** =		x		=	
Multiple Dependent						=	

Large Fee Code	Entity Fee ($)	Small Fee Code	Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

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1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
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SUBMITTED BY				Complete *(if applicable)*	
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Inventor: Murali Jasty

Anterior Cruciate Ligament Substituting Knee Replacement Prosthesis

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to knee replacement prosthesis. More specifically, the invention pertains to prosthetic knee implants, which are implanted in the absence of a functional anterior cruciate ligament and provide a substitute for the function of the anterior cruciate ligament.

2. Background of the Invention

The natural knee joint is complemented by two collateral ligaments, one on the lateral side of the joint and the other on the medial side thereof, each attached both to the tibia and to the femur. The points of attachment of the collateral ligaments to the femur are approximately on the axis of the arc along which the other end of the tibia moves and the knee flexes. In addition to the two collateral ligaments on the outsides of the knee joint, there also are two cruciate ligaments in the middle of the knee joint. One of these cruciate ligaments is attached to the posterior margin of the tibia, while the other is attached towards the anterior margin of the tibia. Both ligaments are attached to the femur in the notch between the condyles approximately on the axis of the collateral ligaments. Often one or both of the cruciate ligaments, particularly the anterior cruciate ligament, deteriorate as a result of the degeneration of the knee joint, which gives rise to the need for a knee prosthesis implantation operation. Hence the surgeon may remove the anterior cruciate ligament, or both of the cruciate ligaments, in the course of the implantation operation.

The absence of the normal function of an anterior cruciate ligament leads to alteration in the gait and other functional activities of the total knee replacement patients and decreases the strength of the muscles about the knee. Many recent studies have shown that total knees without functioning anterior cruciate ligament move in an abnormal fashion with the tibial femoral contact areas lying more posteriorly in full extension than in the normal intact knee with functioning anterior cruciate ligament and moving anteriorly in paradoxical fashion with further knee flexion (see for example, Komistek *et al.*, *J Arthroplasty*17(2):209-216, 2002). These positions and movements which are the reverse to those occurring in normal knee produce abnormal knee kinematics, which can lead to alterations in the gait and functional activities of the patients who often report difficulties with activities such as stair descent. Furthermore, these alterations also decrease the efficiency of the quadriceps mechanism which decreases the strength of the knee.

The prosthetic knee also is subjected to excessive wear due to large amounts of sliding between the femoral and tibial bearing surfaces, which compromises the longevity of the total knee replacements. The tibial component is also subjected to abnormal rocking stresses due to the deviation of the tibial femoral contact points anteriorly and posteriorly from the midline during gait.

Knee prostheses, as known in the art (for example, US Patent no. 6,264,697), have guided surfaces throughout the range of motion for control of anterior-posterior displacement of the tibia. While this appear beneficial, in reality the motion is determined by the remaining of collateral and cruciate ligaments. Any attempts to control this sliding motion, through out the range of flexion by guided surfaces, would be difficult.

Previously known knee prosthesis contains tibial guide surface, which has an anterior and posterior upward sweep, which engages in recesses in the femoral component to contribute stability. Thus, the middle surface of the guide surface is concave, when viewed from the top, with projections on the anteriorly and posteriorly surfaces with articulating surfaces on the posterior and anterior aspect, respectively. This would create abnormally high forces, which would tend to cause tilting of the liner; therefore, the tray at terminal extension and flexion, when the femoral cam contacts the anterior most and posterior most aspects of the tibial liner.

Because, the contact areas are far from the midline of the tibial component. These tilting forces can cause premature loosening of the tibial component or breakage or disengage of the liner from the tray.

A cam on the femoral side engages the guide surface on the tibia or a guide surface which connects the medial and lateral condyles of the femur. The space required to put the cam or the guide surface which extends all the way posteriorly results in excessive removal of the femoral bone in the intercondylar region.

Knee replacement prosthesis can provide a substitute for the function of an anterior cruciate ligament, particularly in cases where a knee joint has ceased to function as a result of deformative joint disorders, rheumatism, or external injury, *etc.* Prior to the present invention, currently available knee replacement prostheses are substantially comprised of a femoral component in which two protruding surfaces, *i.e.*, medial and lateral protruding surfaces, are joined in a front and back relationship to form a femoral condylar portion, and a tibial component. Recessed surfaces in the tibial component support the femoral condylar portion so that the femoral condylar portion is capable of a sliding movement. A rolling movement are joined in a front and back relationship to form a tibial condylar portion. The femoral condylar portion, in this case, has a medial condylar section and a lateral condylar section, and both of these portions are formed so that the trajectory connecting the lowest points of the two portions constitutes an approximate circular-arc curve in two dimensions. In a conventional prosthetic knee, imaginary extended lines of this approximate circular-arc curve in the anteroposterior direction are set parallel to each other. This parallel setting sets limitations on the region of possible movement of the prosthetic knee. Therefore, it is difficult to achieve maximum flexion with such approaches.

Also, currently available total knee replacement prostheses implants generally require the sacrifice of ligaments and natural bone in order to accommodate the mechanism which attempts to drive and contain the replacement knee in a more normal fashion. The mechanism usually includes a prominent eminence on the tibial component and a relatively large recess in the femur to accommodate the eminence. Such replacement prostheses thus require more radical surgery

and increase the shear stresses encountered at the interface between the implant and the natural bone.

Total knee replacements provide dramatic relief of pain and improvement of functions for patients with end stage arthritis of joints. However, most of the currently available prosthetic knee implants employed for the total replacement of the natural knee joint do not adequately replicate the function of the anterior cruciate ligament, which is either absent prior to the replacement procedure or is sacrificed during the procedure. In contrast, the posterior cruciate ligament is often present regardless of the extent of the arthrosis and great care is exercised either preserve the function of the posterior cruciate ligament during the replacement procedure or substitute its function by specific features in the design of the prosthetic components.

Several US Patents describe various aspects of artificial knee joint prosthesis and significance of cruciate ligaments function (see for example, 5413604, 5358527, 6406497, and 6342075). Several other US patents describe various components of knee joint including femoral and tibial (see for example, 5658342, 5935173, 6074425, 6558421, 5219362, 4216549, 6080195, 6413279, and 5011496) components. Various US patents also disclosed total knee replacement prosthesis which flexes to a complete flexion of up to 130° (see for example, 6264697, 4959071, 5147405, 6190415, 5282869, 5997577, and 6152960).

However, until the instant invention, none disclosed a total knee replacement prosthesis, which can provide a substitute for the function of the cruciate ligaments, including the function of an anterior cruciate ligament.

SUMMARY OF THE INVENTION

One aspect of the invention provides to knee replacement prostheses, wherein the prostheseis comprise a femoral component having a pair of condylar surfaces and an intercondylar region; and a tibial component having a tibial platform and a bearing component, such as a non-mobile bearing, which articulate with the femoral component, wherein a protrusion or a tibial post from the bearing component articulates with the intercondylar portion of the

femoral component. The prostheses, if desired, can provide substitute for the function of the cruciate ligaments, including the function of an anterior cruciate ligament.

Another aspect of the invention provides knee replacement prostheses, wherein the prostheses comprise a femoral component having a pair of condylar surfaces and an intercondylar region; and a tibial component having a tibial platform and a bearing component, such as a non-mobile bearing, which articulate with the femoral component, wherein a protrusion or a tibial post from the bearing component articulates with the intercondylar portion of the femoral component, wherein the tibial post is not offset sagitally from center of curvature of the femoral condylar surfaces, wherein anterior surface of the post is curved to allow femoral-tibial axial rotation. The prostheses, if desired, can provide substitute for the function of the cruciate ligaments, including the function of an anterior cruciate ligament.

In another aspect, the invention provides a knee replacement prosthesis, wherein the prosthesis comprises a femoral component having a pair of condylar surfaces and an intercondylar region; and a tibial component having a tibial platform and a bearing component, such as a non-mobile bearing, which articulate with the femoral component, wherein a protrusion or a tibial post from the bearing component articulates with the intercondylar portion of the femoral component, wherein the tibial post is not offset sagitally from center of curvature of the femoral condylar surfaces, wherein anterior surface of the post is curved to allow femoral-tibial axial rotation, wherein the femoral and tibial components are shaped in such a way that the femoral intercondylar surface has a radius of curvature at its distal most aspect which is slightly smaller than the radius of curvature of the anterior surface of the tibial projection, thereby providing a camming action, wherein the anterior articular surface of the tibial component is curved with a radius of curvature of the condylar surfaces which are about the same radius of curvature or slightly larger radius of curvature of the corresponding anterior condyles of the femoral component. The prosthesis, if desired, can provide a substitute for the function of the cruciate ligaments, including the function of an anterior cruciate ligament.

Yet in another aspect, the invention provides a method of repairing a damaged knee of a patient in need by implanting a total knee replacement prosthesis comprising the steps of:

(a) providing a femoral component having a pair of condylar surfaces and an intercondylar region; and

(b) providing a tibial component having a tibial platform and a bearing component, such as a non-mobile bearing, which articulate with the femoral component, wherein a protrusion or a tibial post from the bearing component articulates with the intercondylar portion of the femoral component, wherein the tibial post is not offset sagitally from center of curvature of the femoral condylar surfaces, wherein anterior surface of the post is curved to allow femoral-tibial axial rotation, wherein the femoral and tibial components are shaped in such a way that the femoral intercondylar surface has a radius of curvature at its distal most aspect which is slightly smaller than the radius of curvature of the anterior surface of the tibial projection, thereby providing a camming action, wherein the anterior articular surface of the tibial component is curved with a radius of curvature of the condylar surfaces which are about the same radius of curvature or slightly larger radius of curvature of the corresponding anterior condyles of the femoral component, thereby providing a total knee replacement prosthesis. The prosthesis, if desired, can provide a substitute for the function of the cruciate ligaments, including the function of an anterior cruciate ligament.

Still yet in another aspect, the invention provides a method of making a total knee replacement prosthesis comprising:

(a) obtaining a femoral component having a pair of condylar surfaces and an intercondylar region;

(b) obtaining a tibial component having a tibial platform and a bearing component;

(c) articulating the tibial platform and the bearing component with the femoral component;

(d) articulating a protrusion or a tibial post from the bearing component with the intercondylar portion of the femoral component;

(e) shaping the femoral and tibial components in such a way that the femoral intercondylar surface has a radius of curvature at its distal most aspect which is slightly smaller

than the radius of curvature of the anterior surface of the tibial projection, thereby providing a camming action; and

(f) curving the anterior articular surface of the tibial component with a radius of curvature of the condylar surfaces which are about the same radius of curvature or slightly larger radius of curvature of the corresponding anterior condyles of the femoral component, thereby providing a total knee replacement prosthesis. The prosthesis, if desired, can provide a substitute for the function of the cruciate ligaments, including the function of an anterior cruciate ligament.

Unless otherwise defined, all technical and scientific terms used herein in their various grammatical forms have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are described below. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not limiting.

Further features, objects, and advantages of the present invention are apparent in the claims and the detailed description that follows. It should be understood, however, that the detailed description and the specific examples, while indicating preferred aspects of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a diagrammatic illustration of a tibial prosthetic knee implant containing two condylar surfaces ((2) and (4)) and an intercondylar projection (6). Anterior condylar surfaces ((8) and (10)) are curved and elevated anteriorly to conform to the anterior femoral component.

Figure 2 depicts separated femoral and tibial components to illustrate the engaging surfaces on the tibial condyles ((**8**) and (**10**)) and on the tibial component projection (**12**). The femoral component shows the anterior femoral condylar ((**16**) and (**18**)) and the intercondylar portion (**14**).

Figure 3 illustrates a cross sectional view of the femoral and tibial components articulating with each other in full extension in mid flexion. The intercondylar portion of the femoral component (**14**) is engaged with the anterior surface of the tibial projection (**6**), the anterior femoral condylar ((**16**) and (**18**)) is slided over the anterior tibial condyles ((**8**) and (**10**)).

Figure 4 depicts an exploded view of the femoral and tibial components, showing a tibial component with a central projection (**20**) with anterior (**22**) and posterior (**24**) surfaces, which articulate with distal intercondylar surface of the femoral component (**26**) and an intercondylar cam (**28**).

Figure 5 illustrates a cross sectional view of the femoral and tibial components, depicting a tibial component with a central projection (**20**) with anterior (**22**) and posterior (**24**) surfaces, which is articulated with distal intercondylar surface of the femoral component (**26**) and an intercondylar cam (**28**) during a late flexion.

Figure 6 shows an exploded view of the secondary articulating surfaces, the femoral and tibial components.

Figure 7 depicts a cross sectional view of the tibial post and the femoral stop. The stop prevents the femur from displacing posteriorly in full entension, and the anterior intercondylar region of the tibial liner prevents the femur from displacing anteriorly as the femur is flexed.

Figure 8 shows a cross sectional view of the articulating and the secondary stop surfaces, conforming middle surfaces of tibial lines and the intercondylar groove on the femur.

Figure 9 shows a superior view of the post, the curvature in the transverse or frontal plane, which allow rotation of the tibia on the femur.

Figure 10 depicts a cross sectional view of the post.

DETAILED DESCRIPTION OF THE INVENTION

The invention provides knee replacement prostheses, which can provide a substitute function for the function of the deficient anterior cruciate ligament. The prosthesis comprises a femoral component, having a pair of condylar surfaces and an intercondylar region, a tibial component having a tibial platform and a bearing component, which articulates with the femoral component, and a protrusion from the bearing component, which articulates with the intercondylar portion of the femoral component so as to displace the tibial component anteriorly in extension, and to substitute the function of the deficient anterior cruciate ligament while allowing posterior movement of the tibial component in flexion and axial rotational movement between the femur and the tibia. The bearing component of the invention is preferably a non-mobile component by being fixed to the tibial component.

The femoral and the tibial components of a total knee replacement in which the function of the anterior cruciate ligament is impaired or absent has necessitated the provision of the herein described prosthetic knee implant which can provide a replacement for the anterior cruciate ligament. The invention provides a prosthetic knee implant, which, if desired, can provide a substitute function for the anterior cruciate ligament of a prosthetic knee in which the function of the anterior cruciate ligament is impaired or absent. The prosthetic knee implant of the instant invention also prevents the particular relative motion, for example, movement in a paradoxical fashion, experienced between the femoral and the tibial components in an anterior cruciate ligament deficient knee joint.

According to the invention, the function of anterior cruciate ligament in a prosthetic knee implant is provided by a central projection from the intercondylar region of the tibial component, which articulates with the intercondylar surface of the femoral condyle. The two components are shaped in such a way that the femoral intercondylar surface has a radius of curvature at its distal most aspect which is slightly smaller than the radius of curvature of the anterior surface of the tibial projection so as to provide a camming action and displace the femoral condyle anteriorly in full extension. The anterior articular surface of the tibial component is also curved with a radius of curvature of the condylar surfaces, which are about the same radius of curvature or slightly larger radius of curvature as the corresponding anterior condyles of the femoral component so as

to displace the femoral component posteriorly as the knee is flexed. During the late stages of flexion the femoral component is further displaced posteriorly by the posterior cruciate ligament. Another aspect of this invention involves substitution of the anterior as well as the posterior cruciate ligaments by providing curvatures to the anterior and posterior surfaces of the post in to which the anterior surface of the distal intercondylar surface and a cam engage respectively. Thus, in late flexion the femoral component is further translated posteriorly engaging the cam with the posterior surface of the tibial projection, while in midflexion the femora component is translated posteiorly by the engagement of the anterior condyles of the femoral component with the anterior condyles of the tibial component and in early flexion the femoral component is translated anterior by the engagement of the anterior intercondylar surface of the femoral component with the anterior surface of the tibial projection.

Aspects of the present invention provide variable stops only in late extension and late flexion by the interaction of the tibial post and the intercondylar surfaces of the femur. Thus in most of the mid range of flexion the implant is free to move guided by the ligaments and the articulating surfaces and not by the guide surfaces on the tibia. Besides, the presence of the tibia guide surface, which extends from the front to the back of tibial component, does not allow preservation of the posterior cruciate ligament. The single post of the instant knee prosthesis only occupies the mid-portion of the tibia and does not extend all the way back to the posterior aspect of the tibia; therefore, allows a cut out in the tibial component for preserving the posterior cruciate ligament.

In one aspect, the anteriaor cruciate substituting total knee of the instant invention has a single projection in the middle and with articulating surfaces on the anterior and posterior aspects (rather than posterior and anterior aspects). These articulating surfaces are much closer to the midline of the tibial liner and do not lead to much tilting of the tibial component which could cause loosening or other problems.

According to the instant invention, the intercondylar region which engages with the tibial intercondylar region of the anteriaor cruciate substituting knee only extends to mid position of the tibia and does not require excessive bone resection from the femur.

The knee prosthesis of the invention has a variable stop surface on the posterior and aspects of the tibial post which are not offset sagitally from the major center of curvature of the femoral condylar surfaces, but the radius of curvature is determined by the amount of desired anterior-posterior translation. The knee replacement prosthesis has a variable radius of curvature, preferably less than about 10 mm.

The knee prosthesis of the invention has a tibial post which preferably has a downward sweep on the anterior posterior aspects and preferably does not have an upward sweep.

Unlike conventional knee prosthesis, which controls the anterior/posterior position of the femoral component relative to the tibial platform at any angle of flexion, the knee prosthesis of the invention controls the early and late flexions only and not in the middle flexion. Laxity of the knee is not required to be less than 3 mm in the case of a flexion of greater than about 60 degrees. Thus, the knee prosthesis of the invention can provide a substitute for the function of the cruciate ligaments, including the function of an anterior cruciate ligament.

The invention will be understood more fully, while the objects and advantages will become apparent, in the following detailed description of preferred embodiments of the invention illustrated in the accompanying drawing:

Referring to Figure 1, a diagrammatic illustration of a tibial prosthetic knee implant constructed in accordance with the present invention. The tibial prosthetic knee implant, according to the invention, has a pair of condylar surfaces **(2,4)** and an intercondylar projection **(6)**. The anterior surface of the intercondylar surface contains a curvature with either a fixed radius of curvature or a varying radius of curvature and accepts the intercondylar region of the femoral component in full extension and early flexion (flexion angle is approximately 0 to 20 degrees). The anterior condylar surfaces **(8,10)** also are curved and elevated anteriorly to conform to the anterior femoral component and displace the femur posteriorly in mid flexion (flexion angle is approximately 20 to 80 degrees).

In Figure 2, the femoral and tibial components of a total knee replacement prosthesis are separated to illustrate the engaging surfaces on the tibial condyles **(8,10)** and on the tibial component projection **(12)**. Diagramatically illustrated femoral component shows the anterior

femoral condylar **(16,18)** and the intercondylar portion **(14)**. The intercondylar portion **(14)** engages on the anterior surface of the tibial projection in full extension and early flexion.

As best seen in Figure 3, a cross sectional view of the femoral and tibial components articulating with each other in full extension, according to an aspect of the invention. The intercondylar portion of the femoral component **(14)** engages with the anterior surface of the tibial projection **(12)** in full extension and displaces the femoral component anteriorly. In mid flexion, the anterior femoral condylar **(16,18)** slides over the anterior tibial condyles **(8,10)** and displaces the femoral component posteriorly. The intact posterior cruciate ligament further displaces the femur posteriorly in late flexion (flexion angle is about 80 to about 150 degrees).

Referring now to the drawing, and especially to Figure 4 thereof, is an exploded view of the femoral and tibial components of an anterior and posterior cruciate substituting total knee prosthesis, showing a tibial component with a central projection (tibial post) **(20)** with anterior and posterior surfaces (**22** and **24**, respectively), which articulate with distal intercondylar surface of the femoral component **(26)** and an intercondylar cam **(28)**. During late flexion the interaction and the posterior surface of the femoral projection and the cam displaces the femoral component further posteriorly in a posterior cruciate deficient or substituting total knee. The anterior surface **(22)** of the post **(20)** is curved in the transverse plane, which allows femoral rotation on the tibia.

As illustrated somewhat diagrammatically in Figure 5, is a cross sectional view of the femoral and tibial components of an anterior and posterior cruciate substituting total knee prosthesis, a tibial component with a central projection **(20)** with anterior and posterior surfaces **(22,24)**, which articulate with distal intercondylar surface of the femoral component **(26)** and an intercondylar cam **(28)**, respectively. During late flexion the interaction and the posterior surface of the femoral projection and the cam displaces the femoral component further posteriorly in a posterior cruciate deficient or substituting a total knee.

The invention is further depicted in skectches as best seen in Figures 6 through 10, which do not limit the invention in any manner.

Secondary articulating surfaces, that is, not the weight bearing surfaces but the variable stop surfaces is depicted in figure 6. Figure 6 also showing the intercondylar femur and tibial regions and relative position of the post.

Referring to Figure 7, depicting a cross sectional view of the tibial post and the femoral stop. It is notable that the stop prevents the femur from displacing posteriorly in full entension, and the anterior intercondylar region of the tibial liner prevents the femur from displacing anteriorly as the femur is flexed. After flexion to about 30 to 60 degrees the femur displaces posteriorly by the action of the posterior cruciate ligament or by a cam posteriorly which articulates with the back surface of the tibial post.

Another cross sectional view of the articulating and the secondary stop surfaces is shown in figure 8, which also depicts conforming middle surfaces of tibial lines and the intercondylar groove on the femur to prevent anterior sliding of the femur in early flexion.

A superior view of the post, as depicted in figure 9, is curved in the transverse plane to allow femoral-tibial axial rotation. A cross sectional view of the surface of the post is drawn in figure 10.

The products and processes of this invention involve various types of polymeric materials, for example, any polyolefin, including high-density-polyethylene, low-density-polyethylene, linear-low-density-polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof. Polymeric materials, as used herein, also include polyethylene of various forms, for example, resin powder, flakes, particles, powder, or a mixture thereof, or a consolidated form derived from any of the above.

Ultra-high molecular weight polyethylene (UHMWPE) refers to linear non-branched chains of ethylene having molecular weights in excess of about 500,000, preferably above about 1,000,000, and more preferably above about 2,000,000. Often the molecular weights can reach about 8,000,000 or more. By initial average molecular weight is meant the average molecular weight of the UHMWPE starting material, prior to any irradiation. See US Patent 5,879,400, PCT/US99/16070, filed on July 16, 1999, PCT/US97/02220, filed February 11, 1997, and US Patent publication 20030149125 (US Application Serial No. 10/252,582), filed September 24, 2002.

Crosslinked polymeric material, as used herein, include UHMWPE cross-linked by a variety of approaches, including those employing cross-linking chemicals (such as peroxides and/or silane) and/or irradiation. Preferred approaches for cross-linking employ irradiation. Crosslinked UHMWPE can be obtained according to the teachings of US Patent 5,879,400, US Patent 6,641,617, PCT/US97/02220, and US Patent publication 20030149125 (US Application Serial No. 10/252,582), filed September 24, 2002, the entirety of which are hereby incorporated by reference.

The products and processes of this invention involve various types of metals. The metal can be a cobalt chrome alloy, stainless steel, titanium, titanium alloy or nickel cobalt alloy, for example. Various metal types can also be found in US Serial No. 60/424,709, filed November 8, 2002 (PCT/US03/18053, filed June 10, 2003, WO 2004000159).

The products of this invention can include an "interface", which refer as the niche in medical devices formed when an implant is in a configuration where a component is in contact with another piece (such as a metallic or a non-metallic component), which forms an interface between the polymer and the metal or another polymeric material. For example, interfaces of polymer-polymer or polymer-metal are in medical prosthesis, such as knee replacement prostheses. Various metal/non-metal types and interfaces also can be found in US Serial No. 60/424,709, filed November 8, 2002 (PCT/US03/18053, filed June 10, 2003, WO 2004000159), the entirety of which is hereby incorporated by reference.

In accordance with the invention, the piece forming an interface with polymeric material is, for example, a metal. The metal piece in functional relation with polyethylene, according to the present invention, can be made of a cobalt chrome alloy, stainless steel, titanium, titanium alloy or nickel cobalt alloy, for example.

In accordance with the invention, the piece forming an interface with polymeric material is, for example, a non-metal. The non-metal piece in functional relation with polyethylene, according to the present invention, can be made of ceramic material, for example.

It is to be understood that the description, specific examples and data, while indicating exemplary embodiments, are given by way of illustration and are not intended to limit the

present invention. Various changes and modifications within the present invention will become apparent to the skilled artisan from the discussion, disclosure and data contained herein, and thus are considered part of the invention.

CLAIMS:

1. A knee replacement prosthesis comprises:

(a) a femoral component having a pair of condylar surfaces and an intercondylar region; and

(b) a tibial component having a tibial platform and a bearing component which articulate with the femoral component, wherein a protrusion or a tibial post from the bearing component articulates with the intercondylar portion of the femoral component, wherein the tibial post is not offset sagitally from center of curvature of the femoral condylar surfaces, wherein anterior surface of the post is curved to allow femoral-tibial axial rotation.

2. The knee replacement prosthesis of claim 1, wherein the replacement prosthesis is a substitute for the function of an anterior cruciate ligament.

3. The knee replacement prosthesis of claim 1, wherein the bearing component is non-mobile.

4. The knee replacement prosthesis of claim 1, wherein the knee has a variable radius of curvature of less than about 10 mm.

5. The knee replacement prosthesis of claim 1, wherein the tibial post which has a downward sweep on the anterior posterior aspects.

6. The knee replacement prosthesis of claim 1, wherein the knee controls anterior/posterior position of the femoral component relative to the tibial platform at early and late flexions only and not in the middle flexion.

7. The knee replacement prosthesis of claim 1, wherein anterior surface of the intercondylar surface has a fixed or variable radius of curvature.

8. The knee replacement prosthesis of claim 1, wherein anterior surface of the intercondylar surface accepts the intercondylar region of the femoral component in full extension and early flexion.

9. The knee replacement prosthesis of claim 8, wherein the flexion is about 0 to about 20 degrees.

10. The knee replacement prosthesis of claim 1, wherein anterior condylar surfaces of the tibial component are curved and elevated anteriorly to conform to the anterior femoral component and displace the femur posteriorly in mid flexion.

11. The knee replacement prosthesis of claim 10, wherein the flexion is about 20 to about 80 degrees.

12. The knee replacement prosthesis of claim 1, wherein the intercondylar portion of the femoral component engages the protrusion from the bearing component in full extension and early flexion.

13. The knee replacement prosthesis of claim 1, wherein, at a mid flexion, anterior femoral condylar of the femoral component slides over anterior tibial condyles of the tibial component and displaces the femoral component posteriorly.

14. The knee replacement prosthesis of claim 1, wherein a central projection of the tibial component articulate with distal intercondylar surface of the femoral component and an intercondylar cam.

15. The knee replacement prosthesis of claim 1, wherein intact posterior cruciate ligament displaces femur posteriorly in late flexion.

16. The knee replacement prosthesis of claim 15, wherein the flexion is about 80 to about 150 degrees.

17. A knee replacement prosthesis comprises:

(a) a femoral component having a pair of condylar surfaces and an intercondylar region; and

(b) a tibial component having a tibial platform and a bearing component which articulate with the femoral component, wherein a protrusion or a tibial post from the bearing component articulates with the intercondylar portion of the femoral component, wherein the tibial post is not offset sagitally from center of curvature of the femoral condylar surfaces,

wherein anterior surface of the post is curved to allow femoral-tibial axial rotation, wherein the femoral and tibial components are shaped in such a way that the femoral intercondylar surface has a radius of curvature at its distal most aspect which is slightly smaller than the radius of curvature of the anterior surface of the tibial projection, thereby providing a camming action, wherein the anterior articular surface of the tibial component is curved with a radius of curvature of the condylar surfaces which are about the same radius of curvature or slightly larger radius of curvature of the corresponding anterior condyles of the femoral component.

18. The knee replacement prosthesis of claim 17, wherein the replacement prosthesis is a substitute for the function of an anterior cruciate ligament.

19. The knee replacement prosthesis of claim 17, wherein the bearing component is non-mobile.

20. A method of repairing a damaged knee of a patient in need by implanting a total knee replacement prosthesis comprising the steps of:

(a) providing a femoral component having a pair of condylar surfaces and an intercondylar region; and

(b) providing a tibial component having a tibial platform and a bearing component which articulate with the femoral component, wherein a protrusion or a tibial post from the bearing component articulates with the intercondylar portion of the femoral component, wherein the tibial post is not offset sagitally from center of curvature of the femoral condylar surfaces, wherein anterior surface of the post is curved to allow femoral-tibial axial rotation, wherein the femoral and tibial components are shaped in such a way that the femoral intercondylar surface has a radius of curvature at its distal most aspect which is slightly smaller than the radius of curvature of the anterior surface of the tibial projection, thereby providing a camming action, wherein the anterior articular surface of the tibial component is curved with a radius of curvature of the condylar surfaces which are about the same radius of curvature or slightly larger radius of curvature of the corresponding anterior condyles of the femoral component, thereby providing a total knee replacement prosthesis.

21. The method of claim 20, wherein the replacement prosthesis is a substitute for the function of an anterior cruciate ligament.

22. The method of claim 20, wherein the bearing component is non-mobile..

23. A method of making a total knee replacement prosthesis comprising:

(a) obtaining a femoral component having a pair of condylar surfaces and an intercondylar region;

(b) obtaining a tibial component having a tibial platform and a bearing component;

(c) articulating the tibial platform and the bearing component with the femoral component;

(d) articulating a protrusion or a tibial post from the bearing component with the intercondylar portion of the femoral component;

(e) shaping the femoral and tibial components in such a way that the femoral intercondylar surface has a radius of curvature at its distal most aspect which is slightly smaller than the radius of curvature of the anterior surface of the tibial projection, thereby providing a camming action; and

(f) curving the anterior articular surface of the tibial component with a radius of curvature of the condylar surfaces which are about the same radius of curvature or slightly larger radius of curvature of the corresponding anterior condyles of the femoral component, thereby providing a total knee replacement prosthesis.

24. The method of claim 23, wherein the replacement prosthesis is a substitute for the function of an anterior cruciate ligament.

25. The method of claim 23, wherein the bearing component is non-mobile.

26. The method of claim 23, wherein the knee has a variable radius of curvature of less than about 10 mm.

27. The method of claim 23, wherein the tibial post which has a downward sweep on the anterior posterior aspects.

28. The method of claim 23, wherein the knee controls anterior/posterior position of the femoral component relative to the tibial platform at early and late flexions only and not in the middle flexion.

29. The method of claim 23, wherein laxity is no less than 3 mm when flexion is greater than about 60 degrees.

30. The method of claim 23, wherein anterior surface of the intercondylar surface has a fixed or variable radius of curvature.

31. The method of claim 23, wherein anterior surface of the intercondylar surface accepts the intercondylar region of the femoral component in full extension and early flexion.

32. The method of claim 31, wherein the flexion is about 0 to about 20 degrees.

33. The method of claim 23, wherein anterior condylar surfaces of the tibial component are curved and elevated anteriorly to conform to the anterior femoral component and displace the femur posteriorly in mid flexion.

34. The method of claim 33, wherein the flexion is about 20 to about 80 degrees.

35. The method of claim 23, wherein the intercondylar portion of the femoral component engages the protrusion from the bearing component in full extension and early flexion.

36. The method of claim 23, wherein, at a mid flexion, anterior femoral condylar of the femoral component slides over anterior tibial condyles of the tibial component and displaces the femoral component posteriorly.

37. The method of claim 23, wherein a central projection of the tibial component articulate with distal intercondylar surface of the femoral component and an intercondylar cam.

38. The method of claim 23, wherein intact posterior cruciate ligament displaces femur posteriorly in late flexion.

39. The method of claim 23, wherein the flexion is about 80 to about 150 degrees.

ABSTRACT OF THE DISCLOSURE

There is disclosed a total knee replacement prosthesis, which can substitute the function of an anterior cruciate ligament. A femoral component containing two intercondylar surfaces and an intercondylar region, a tibial component having a tibial platform and a bearing component, and a protrusion from the bearing component also are disclosed.

Figure 1.

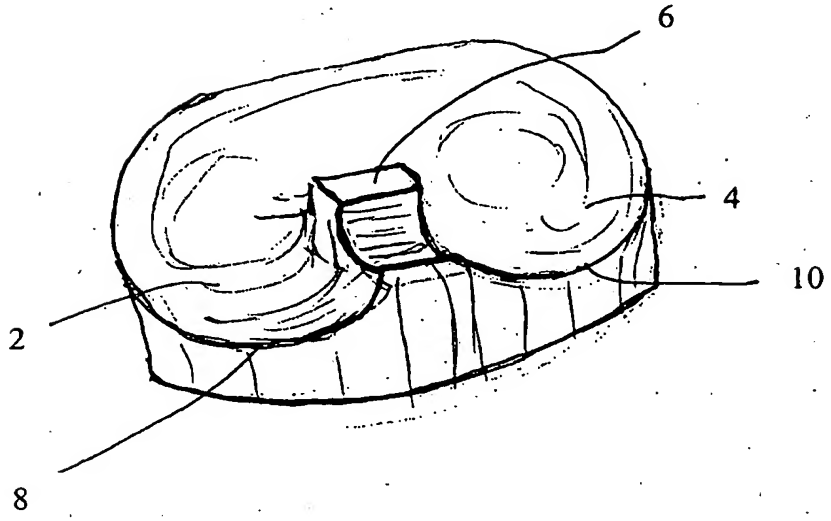

Figure 2.

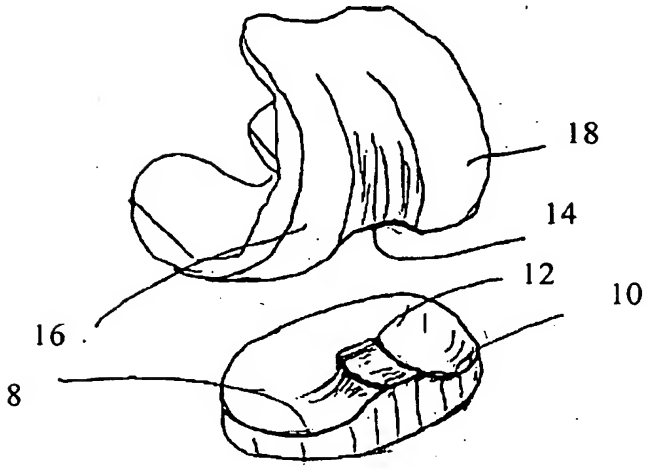

Figure 3.

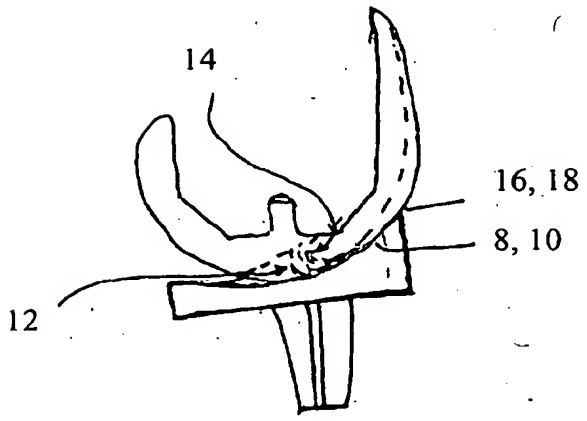

Figure 4.

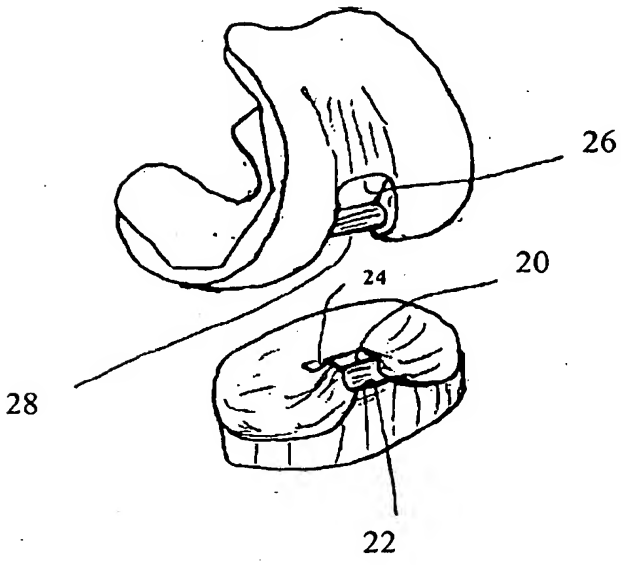

Figure 5.

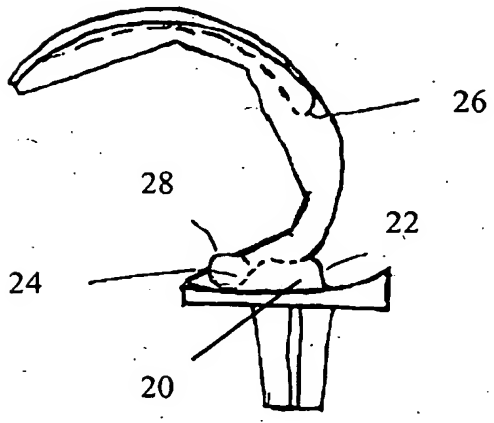

Figure 6.

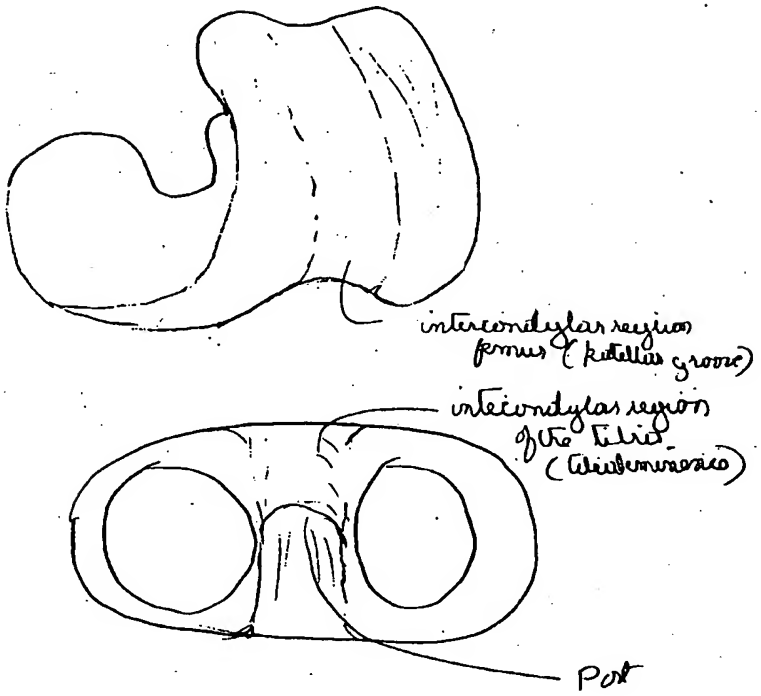
intercondylar region
femur (patellar groove)
intercondylar region
of the tibia
(tibial eminence)
Post

Figure 7.

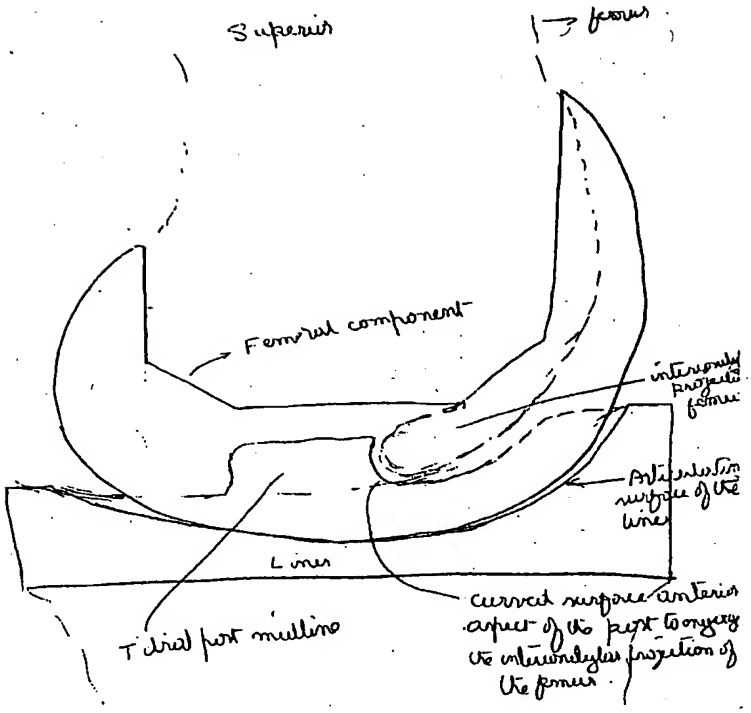

Figure 8.

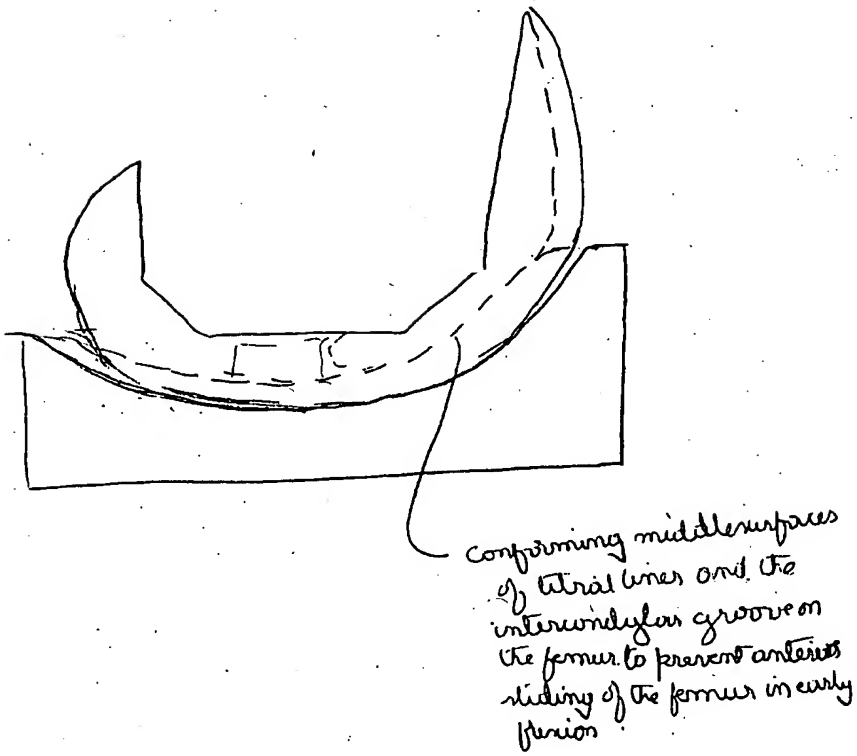
conforming middle surfaces of tibial liner and the intercondylar groove on the femur to prevent anterior sliding of the femur in early flexion

Figure 9.

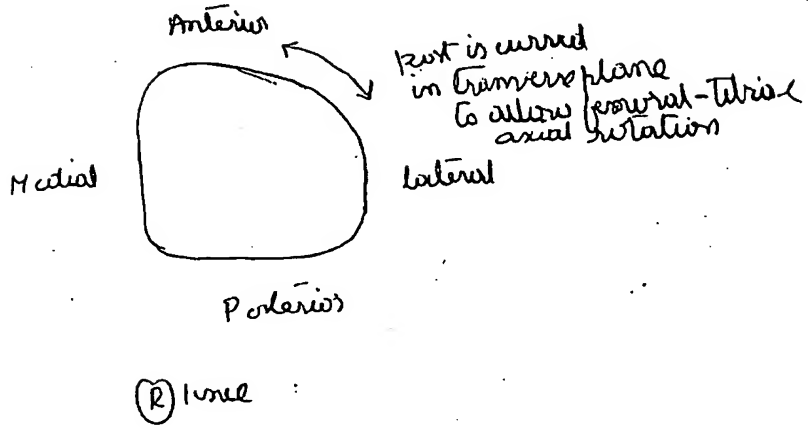
View looking down on the foot
Anterior
foot is curved in transverse plane to allow femoral-tibial axial rotation
Medial
Lateral
Posterior
(R) knee

Figure 10.